

K021928

SEP 6 2002

3. 510(k) Summary

<b>Submitter</b>	Synthes (USA) 1690 Russell Road Paoli, PA 19301
<b>Company Contact</b>	Bonnie Smith (610) 647-9700
<b>Name of the Device</b>	Synthes (USA) Resorbable Fixation System
<b>Predicate Device</b>	Synthes Resorbable Fixation System, Synthes Resorbable Tack System and Synthes Resorbable Meshes and Sheets.
<b>Device Description</b>	<p>Synthes Resorbable Fixation System consists of resorbable plates, meshes, screws, tacks and accessory devices. Synthes Resorbable devices are manufactured from 70:30 poly (L/DL-lactide) and are available in various sizes. Resorbable meshes and sheets may be used as indicated, either alone or in conjunction with internal fixation devices (e.g., metallic plates and screws) that serve to further stabilize the treatment area.</p> <p>Resorbable Fixation System devices are provided pre-sterilized by gamma radiation. They are not intended to be resterilized by the user.</p>
<b>Indications for Use</b>	<p>Synthes Resorbable Fixation System devices (Plates, Meshes, Sheets, Screws and Tacks), are intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Resorbable Meshes, Sheets, Screws and Tacks may be used in non-load bearing applications for :</p> <ul style="list-style-type: none"><li>▪ Maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas</li><li>▪ Preventing soft tissue prolapse at bone graft donor sites, e.g., the iliac crest</li></ul>
<b>Contraindications</b>	These devices are not intended for use in full load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Resorbable Fixation devices are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 6 2002

Ms. Bonnie J. Smith  
Sr. Regulatory Affairs Associate  
Synthes (USA)  
1690 Russell Road  
Paoli, Pennsylvania 19301

Re: K021928

Trade/Device Name: Synthes (USA) Resorbable Fixation System  
Regulation Number: 872.4760, 882.5330, 882.5360 and 882.4300  
Regulation Name: Bone Plate, Preformed Nonalterable Cranioplasty Plate,  
Cranioplasty Plate Fastener and Manual Cranial Drills, Burrs, Trephines  
And their Accessories  
Regulatory Class: II  
Product Code: JEY  
Dated: June 10, 2002  
Received: June 12, 2002

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

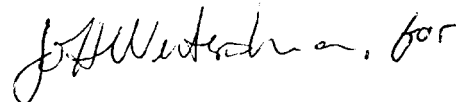
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in dark ink, appearing to read "J. A. Ulatowski, for".

Timothy A. Ulatowski  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

2. **Indications for Use**

K021928

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510(k) Number (if known): K021928

Device Name: Synthes (USA) Resorbable Fixation System

Indications

Synthes Resorbable Fixation System devices (Plates, Meshes, Sheets, Screws and Tacks), are intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Resorbable Meshes, Sheets, Screws and Tacks may be used in non-load bearing applications for:

- Maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas
- Preventing soft tissue prolapse at bone graft donor sites, e.g., the iliac crest

Contraindications

These devices are not intended for use in full load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Resorbable Fixation System devices are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-the-Counter Use ☐  
(Per 21 CFR 801.109)

Synthes (USA)  
Premarket Notification 510(k):  
Synthes Resorbable Fixation System – Combined Indications

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Susan Pinner  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K021928004